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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,606	11/10/2003	Lisa Benincosa	P32185C1	4699

7590 10/18/2006

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EXAMINER	
WILLIAMS, LEONARD M	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 10/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/705,606	BENINCOSA ET AL.	
	Examiner	Art Unit	
	Leonard M. Williams	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 22-37 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 22-37 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/7/2006 has been entered.

Status of Claims

The amendment/remarks received in the office on 8/7/2006 amending claims 22-37 has been entered. Claims 22-37 are currently pending.

Response to Amendment/Remarks

The amendment of the claims are such that they do not overcome the 103(a) rejection as written, therefore the 103(a) rejection of claims 22-37 as detailed in the previous office action is maintained.

The applicants have argued that the examiner has failed to demonstrate a prima facie case of obviousness. The examiner respectfully disagrees. The prior art teaches the ranges currently claimed, the dosages currently claimed, and the compounds

currently claimed. The current claims while asserting functional limitations and/or intended use preamble limitations such as sustained releases pharmaceutical composition the applicants have not described in the claims any formulations such that render the claims different from the prior art. Further as the examiner has clearly detailed in the 103(a) rejection of the prior office action it would be obvious to one of ordinary skill in the art to formulate a known compound into a sustained release composition, especially when the claimed sustained release pharmaceutical composition does not detail how it is formulated as such, but merely asserts a sustained release capability.

For the reasons described above and detailed previously the 103(a) rejection is maintained and is detailed below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 22-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pool et al. (US Patent No. 5741803).

The examiner wishes to point out that the current specification discloses, on page 3, that compound I (the presently claimed compound) has a unit dose suitably comprising 2-12 mg or preferably 4-8 mg in a pharmaceutically acceptable form. The current specification discloses, on page 8, that the medicaments may be administered from 1-6 times a day, suitably 1 or 2 times a day, and preferably once a day.

Pool et al. teach, in col. 1 lines 10-25, compounds of formula (I) useful in the treatment and/or prophylaxis of Type II diabetes and related conditions including hyperlipidemia, hypertension and cardiovascular disease. Pool et al. teach, in col. 2 lines 40-45, a preferred compound of formula (I) is 5-[4-[2-(N-methyl-N-92-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione maleic acid (the maleic acid salt of the currently claimed compound I). Pool et al. teach, in col. 5 lines 1-50, that the

composition of formula (I) can be formulated for oral administration and can be delivered as unit dosages wherein the unit dose will normally contain an amount of the active ingredient in the range from 0.1-1000 mg, and can be administered from 1-6 times a day.

Pool et al. does not explicitly teach a sustained release pharmaceutical composition adapted to provide a particular plasma concentration.

It would have been obvious to one of ordinary skill in the art at the time the invention was made that the composition of Pool et al. could be formulated as a sustained release pharmaceutical composition adapted to provide a particular plasma concentration, as Pool et al. clearly indicated that the compounds were to be administered from 1-6 times a day in concentrations of from 0.1-1000 mg and in order to achieve effective plasma concentration levels in low compound concentrations and/or low daily dosages as indicated one would have to formulate the compounds such that they would be delivered at a sustained rate. Further it is well known in the art to formulate pharmaceutical compositions as sustained release compositions in order to more effectively deliver the compositions due to short half-lives and/or to better treat/control a particular disease state.

The examiner respectfully points out the following: "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are

necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leonard M. Williams whose telephone number is 571-272-0685. The examiner can normally be reached on MF 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LMW

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER